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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,244	10/31/2005	Winfried Miller	3024-114	3986

46002 7590 03/26/2007
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EXAMINER

ARIANI, KADE

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/555,244	Applicant(s) MILLER, WINFRIED	
	Examiner Kade Ariani	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 28-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The preliminary amendment filed on October 31, 2005, has been received and entered.

Claims 26 and 27 have been canceled.

Claims 1-25, and 28-31 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leipner et al. (BioDrugs, 2001, Vol. 15, No. 12, 779-789) in view of Cochran (US Patent No. 6,048, 846) and further in view of Friedman & Sklan (British Journal of Nutrition, 1989, Vol. 62, p. 439- 449) and further in view of Ramussen & Seljelid (Journal of Cellular Biochemistry, 1991, Vol. 46, p.60-68).

Claims 1-25, and 28-31 are drawn to a composition comprising one or more hydrolases and (a) one or more antioxidants which are selected from the group of vitamins having activity, carotenoids, selenium-containing substances, and ubiquinones,

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(b) one or more amino acids, (c) one or more polysaccharides or (d) combinations thereof, one or more polyphenols, the composition wherein hydrolases are plant proteases and/or animal proteases, plant proteases are bromelain, bromelain-containing pineapple extracts, papain, papain-containing papaya extracts or combination thereof, the animal proteases are trypsin, or chymotrypsin or combination thereof, vitamins are selected from vitamin A, C and E or the esters of vitamin A, and E, coenzyme Q-10, L-arginine, L-glutamine, L-glycine, carotenoids, a food product, a medicament, a dietetic treatment method to regulate the immune system and to treat inflammatory disorders.

Leipner et al. teaches therapeutic use of a composition of proteolytic enzymes comprising one or more hydrolases, papain, bromelain, trypsin, chymotrypsin (see p.779 Abstract and Introduction), flavinoids rutin, also known as citrus bioflavonoid (p. 780, Col. 2, Lines 19-21), oral administration of the composition (p. 780, Col.1, last paragraph).

Leipner et al. does not teach carotenoids, sodium selenite, Coenzyme Q-10, vitamins with antioxidant activity, amino acids and polysaccharides. However, Cochran teaches a composition that strengthened and enhanced the ability of body to fight diseases (Col.4, Lines 1-4) comprising of one or more hormone, one or more amino acids, one or more enzymes, vitamins and antioxidants, and one or more minerals. Cochran further teaches Coenzyme Q-10, lycopene and β -carotene (carotenoids), vitamin C and E, selenium, L-arginine, L-glutamine, glycine, L-methionine (Col. 4, Lines 45-56, also see Fig. 1).

It would have been obvious to one of the ordinary skill in the art to combine the teachings of Leipner et al. Stauder et al. and Cochran to obtain a composition to strengthen the immune response and to treat inflammatory-rheumatic disorders by combining the claimed ingredients because a composition of proteolytic enzymes comprising, papain, bromelain, trypsin, chymotrypsin, flavinoids, antioxidants, amino acids, were being used anti-inflammatory therapy and to strengthen the immune response.

Moreover, at the time the invention was made the immunostimulatory effect of β -glucan was very well known in the art (Ramussen & Seljelid, see Abstract and Introduction) together with the fact that vitamin A (retinyl) acetate deficiency was led to severe immune response impairment (Friedman & Sklan, see abstract and Introduction) therefore including β -glucan and vitamin A acetate to a composition targeted to strengthen the immune defenses of the body would have been obvious.

Accordingly, the invention taken as whole is *prima facie* obvious.

Conclusion

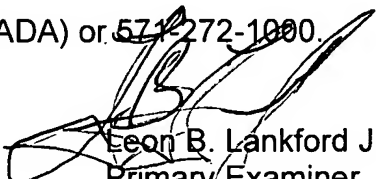
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651



Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651